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EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	PAPER NUMBER
1616	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,202	BARTHOLOMAUS ET AL.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/02/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 are pending examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "simultaneously spraying of an aqueous solution of the hydrophilic polymers and of the active ingredient and/or nutrient and of an aqueous solution of the polyacrylic acid derivative" which is indefinite. The metes and bounds of the claim cannot be deciphered. It is unclear if the aqueous solution comprises the hydrophilic polymer only or if the aqueous solution comprises the hydrophilic polymer and the active ingredient and/or nutrient.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a

question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 2 recites "an optionally crosslinked polyacrylic acid", and the claim also recites "preferably a polyacrylic acid crosslinked with allylsucrose or allylpentaerythritol and/or a polyacrylic acid crosslinked with divinylglycol, where appropriate neutralized with calcium which is the narrower statement of the range/limitation.

In the present instance, claim 3 recites the broad recitation "hydroxyproplymethylcellulose, hydroxyethylcellulose and/or methylcellulose", and the claim also recites "preferably hydroxypropylmethylcellulose" which is the narrower statement of the range/limitation.

In the present instance, claim 4 recites the broad recitation "the weight ratio of hydrophilic polymers to polyacrylic acid derivatives is from 5:1 to 5:4", and the claim also recites "preferably 5:2 to 5:3" which is the narrower statement of the range/limitation.

Claim 6 recites "and where appropriate an adhesive layer" is indefinite. It is unclear if the adhesive layer is present or optional in the invention as well has how the term "where appropriate" is to be interpreted. The metes and bounds of the claim

cannot be deciphered. For the purpose of examination the claim has been interpreted as optionally comprising an adhesive layer.

Claim 7 recites “at least one active ingredient containing layer has a concentration gradient of the active ingredient” which is indefinite. The specification does not define the metes and bounds of this term.

Claim 8 recites “the covering layer is impermeable for the active ingredient” which is indefinite. The specification does not define the metes and bounds of this term because an active ingredient is not specified.

Claim 9 recites the limitation "in that it is covered with a protective layer" in claim 1. There is insufficient antecedent basis for this limitation in the claim because it is unclear what “it" is referring to. Is “it" the final dosage form, just the active ingredient or an intermediate formulation in the process of claim 1?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The factors considered in the written description requirement are (1) *level of skill and knowledge in the art,* (2) *partial*

structure, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention.*

While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

The specification discloses “within an active ingredient-containing layer it is possible for example to control the release by a concentration gradient of the active ingredient". However, no examples are provided of particular structures or compounds with this effect.

Second, the specification discloses “the covering layer preferably consists of a water-insoluble polymer and is impermeable for the active ingredient". However, no examples are provided of particular structures or compounds with this effect.

The claim 7 is drawn to “at least one active ingredient containing layer has a concentration gradient of the active ingredient”.

The claim 8 recites “the covering layer is impermeable for the active ingredient”.

University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (Fed.Cir. 2004), states that the description must convey what the compound is, not just what it does (see page 1895). A review of the language of the claim indicates that these claims are drawn to the action of “the concentration gradient of the active ingredient” rather than a particular structure. The claims fail to identify a particular structure to which the active ingredient is limited to. Therefore there are no structure disclosed and the written description requirement is not satisfied.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nara et al. (US 6,245,351) in view of Horstmann et al. (6,800,329).

Applicant's Invention

Applicant claims a process of producing a dosage form in film form comprising at least one active ingredient containing and/or nutrient-containing layer based on hydrophilic polymers crosslinked with at least on polyacrylic derivative, characterized by the steps of a) simultaneously spraying an aqueous solution of the hydrophilic polymers and the active ingredient containing and/or nutrient and of an aqueous solution of the polyacrylic acid derivative, b) removing the water by drying. Claim 2 states the polyacrylic acid derivative is an optionally crosslinked polyacrylic acid. Claim 3 states the hydrophilic polymer is hydroxypropylmethylcellulose, hydroxyethylcellulose and/or methylcellulose. Claim 4 specifies the weigh ratio of hydrophilic polymer to polyacrylic acid is 5:1 to 5:4.

Applicant claims the product made by the process.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Nara et al. teach a controlled-release composition comprising a drug-containing core coated with a coating composition (abstract). Nara et al. teach a method of producing the drug includes steps wherein the core is sprayed over an inert carrier particle (column 5, lines 54-61). Example 3 discloses a process of preparing morphine hydrochloride solution to spray chill and yield spherical particles (column 9, lines 30-45). The particles were granulated to fine granules and the spray coated solution comprising ethyl cellulose and crosslinked acrylic polymer in the ratio is (70:30). Example 7 discloses a method where in the morphine hydrochloride in formulated into an aqueous solution with hydroxypropylcellulose (column 10, lines 32-63). The resulting mixture was spray coated with a coating solution comprising ethyl cellulose, hydroxypropylmethyl cellulose and a crosslinked polyacrylic polymer (70:20:10).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Nara et al. do not teach a step of drying the mixture or that the dosage is in film form. It is for this reason that Horstmann et al. is combined.

Horstmann et al. teach a process for the production of sheet-like administration forms by way of coating and drying a solvent obtaining spreadable mass on a substrate with drying (abstract). The hydrophilic base substances include polyacrylic acid homopolymers and cellulose derivatives (column 2, lines 31-41). The mixture is dried and the product obtained is stable enough to be removed from the support. Claim 1 recites a process comprising: applying onto a surface of a substrate a coating of a spreadable solution comprising at least one hydrophilic polymer.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Nara et al. and Horstmann et al. to further include producing a film form and with the step of drying the solution. One would have been motivated to include drying the solution to form a film because Horstmann et al. teach that drying the mixture is necessary for the film to form.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iwakura et al. (US 4,777,046).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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